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No. 91-81

Supreme Court, U.S.
FILED
SEP 24 1991
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

BARR LABORATORIES, INC.,
Petitioner,

v.

LOUIS W. SULLIVAN,
Secretary of Health and Human Services, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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PETITIONER'S REPLY MEMORANDUM

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September 1991

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ARGUMENT

The FDA's brief in opposition offers four arguments. None merits a denial of the writ. We address those arguments in the order presented by the FDA.

1. The Administrative Procedure Act ("APA") provides that a "reviewing court shall . . . compel agency action unlawfully witheld." 5 U.S.C. § 706(1) (1988). As already has been noted by the petitioner ("Barr"), "[t]he question presented is whether a court that has found such unlawful withholding may refuse to grant relief to

the aggrieved party." Barr Pet. (i). The FDA claims that Barr did not raise this question below and that the Court of Appeals did not pass on this question. Brief in Opposition at 5. The FDA's contentions are incorrect. Barr raised in the Court of Appeals the question presented by the petition, Barr Pet. at 4-5 and App. 10a-11a, and the Court of Appeals necessarily passed on that question. *See Thompson v. United States Dep't of Labor*, 813 F.2d 48, 52 (3d Cir. 1987) (consideration of availability of APA-based relief must *precede* consideration of common law mandamus).

The FDA's reliance upon *Lawn v. United States*, 355 U.S. 339, 362 n.16 (1958), also is misplaced. *See* Brief in Opposition at 7. *Lawn* held only that a petitioner's failure to raise in the court of appeals an allegedly erroneous trial court ruling rendered that claim of error—absent a showing of "exceptional circumstances"—unfit for review in this Court. 355 U.S. at 362 n.16. The petitioner in *Lawn* also failed to raise the "new" issue in the petition for certiorari. *Id.* Here, by contrast, Barr has raised the issue both in the Court of Appeals and in the petition. See Barr Pet. (i), App. 10a-11a.

The FDA erroneously claims that Barr's "sole" basis for certiorari is that the judicial review provisions of the APA allow a court no equitable discretion. Brief in Opposition at 5. Barr's claim, however, goes only to the narrower class of cases wherein the reviewing court finds —as the Court of Appeals did here—that the agency has failed to act in the face of a mandatory statutory deadline. The FDA fails to observe the important distinction between such a case, where the action has been unlawfully withheld, and one in which there is no express statutory deadline and the issue hence is whether the action has been unreasonably delayed. Barr does not question the availability of judicial discretion in the latter circumstance, which is not present here.

2. The suggestion of an inter-circuit conflict was raised not by Barr but by the National Association of

Pharmaceutical Manufacturers ("NAPM"), the cross-petitioner in No. 91-300. Barr notes only that the Court of Appeals' erroneous decision on an important question of federal law is itself an ample basis for review by this Court. Sup. Ct. R. 10.1(c).

3. The FDA contends incorrectly that where unlawful withholding of FDA action is brought before a Court of Appeals, the protections of the APA become unavailable. Brief in Opposition at 8-11. The APA provides that when agency action has been unlawfully withheld, a reviewing court must compel that action. The FDA concedes that this standard applies when an FDA *denial* of an ANDA is brought before a Court of Appeals, Brief in Opposition at 8, and whenever the FDA's unlawful withholding of action is reviewable by a *District Court.*[1] *Id.* at 11 n.7.

The FDA claims, however, that the provision granting jurisdiction to the Court of Appeals, 21 U.S.C. § 355(h) (1988), extends only to FDA's *refusal* to approve an ANDA. Brief in Opposition at 10. The FDA then argues that where the Court of Appeals is reviewing the FDA's *failure to act* on an ANDA, the Court of Appeals may act only under the All Writs Act and the APA plays no role. *Id.* at 9-11.

The FDA's argument is tortured and unconvincing. As the Court of Appeals found, Congress desired strongly to ensure timely action on ANDAs. Barr Pet. at 8a-9a. Congress enacted section 355(j)(4)(A), with its mandatory 180-day deadline, in an effort to reach that goal. *Id.* at 3a-4a, 8a-9a. In essence, the FDA contends that if the FDA is guilty of the very conduct that Congress sought to prohibit—failure or refusal to obey the statutory

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[1] At least in the D.C. Circuit, the *TRAC* decision precludes District Court review of the FDA's failure to act on an ANDA. *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70 (D.C. Cir. 1984).

command—Barr has no right to relief.[2] This means in turn that if the FDA desires to avoid review of its handling of an ANDA, the FDA is better advised to refuse to act than to reject the ANDA following a timely review. That is the opposite of what Congress intended. Nothing in the text or the legislative history of section 355(h) supports the FDA's view. The APA standard applies here, and the Court of Appeals was required to compel the unlawfully withheld FDA action.[3]

4. The FDA's discussion of the merits effectively makes Barr's point. The FDA argues that the APA's use of the word "unreasonable" implies an equitable discretion to refuse relief. Brief in Opposition at 11. The FDA would avoid review by having this Court focus on the wrong branch of section 706(1), and upon legislative history that is at best ambiguous instead of the plain meaning of the APA.

The Court of Appeals correctly found that the 180-day deadline of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(4)(A) (1988), is *mandatory*. Barr Pet. at 4a. That finding makes the issue in this case one not of action "unreasonably delayed" but of action "unlawfully withheld." *See* Barr Pet. at (i), 10 n.4. The FDA's argument regarding the unreasonable delay branch of section 706(1) accordingly has no place in this case. The FDA cannot avoid the statute's command that "[t]he reviewing court *shall* . . . compel agency action unlawfully withheld." 5 U.S.C. § 706(1) (1988) (emphasis added).

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[2] Presumably the FDA believes that the APA requirement that an agency must decide matters before it "within a reasonable time," 5 U.S.C. § 555(b) (1988), also is inapplicable to the FDA because final ANDA decisions are reviewable in the Court of Appeals rather than the District Court.

[3] As to what an order compelling action might provide, see footnote 5 of Barr's petition.

The FDA's resort to legislative history also is misplaced. Brief in Opposition at 11-12. The wording of the statute itself could not be clearer. Hence no resort to legislative history is necessary.[4] *Business Guides, Inc. v. Chromatic Communications Enterprises, Inc.*, 111 S.Ct. 922, 928 (1991). In any event, the weight of the legislative history supports a literal reading of the statute. See Barr Pet. at 9.

CONCLUSION

A writ of certiorari should issue to review the judgment of the Court of Appeals.

Respectfully submitted,

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[4] The same is true of the self-serving *Attorney General's Manual on the Administrative Procedure Act*, cited at page 12 n.8 of the Brief in Opposition.